

Case Study #1

To develop a multi-layered electrode with different adherence qualities to allow bio-signal retrieval and easy removal post use

Overview

The customer's objective was to source expertise to enable the product to stick to one surface permanently whilst the opposite surface was to adhere securely to their device to prevent liquid ingress and also be easily removed to reduce the cleaning process by clinical staff.

Investigation into multilayered adhesive substrates were successful in achieving the required performance. Bio-signals were unaffected during use in a submerged environment and the product was successfully removed from the device after use with minimal residue.

CHALLENGE



Adhesives are generally provided as a single layered material with similar performance on each side. During concept testing phase, it was observed that single layered adhesives would meet only one of the two desired device performance properties.

ACTION TAKEN



Intensive discussions with material providers and material converters enabled Intelesens to identify and test a variety of different adhesives laminated to each other. Each adhesive had its own specific properties. After the culmination of various bench tests, a lamination of two optimally performing adhesives were chosen for pre-clinical tests on volunteers.

RESULT






The pre-clinical tests proved that the lamination of two different adhesives enabled all properties of the product to be achieved for bio-signal retrieval and also for post monitoring cleaning. The materials selected and tested were medical grade and met the necessary regulatory requirements for medical devices.

Key Observations

- Investigation and design improvements developed in this project would allow for other opportunities to be explored with prospective clients requiring similar electrode performance.
- The group enhanced their knowledge of material properties and lamination techniques during this project.
- Expertise developed during this project enhanced the portfolio of materials and the available in-house for broader applicability.

intelesens))

 www.intelesens.com
 17 Heron Road, Belfast, BT3 9LE
 electrodes@intelesens.com



Longest shelf life on the market of 5.5yrs



Manufactured to the highest regulatory standards



Adult & paediatric options



Technical file generation & design change control